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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KARL KOLTER,
MICHAEL SCHONERR,
and
HERMANN ASCHERL,
Appellants

Appeal 2008-3377
Application 09/811,546[1]
Technology Center 1600

Decided: July 10, 2008

Before ADRIENE LEPIANE HANLON, CAROL A. SPIEGEL, and DONALD E. ADAMS, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] Application 09/811,546, filed 20 March 2001, claims benefit under 35 U.S.C. § 119 of German application 10015479.4, filed 29 March 2000. The real party in interest is said to be BASF Aktiengesellschaft (Appeal Brief under 37 C.F.R. § 41.37, filed 23 August 2007 ("Br."), at 2).

I. Statement of the Case

Appellants appeal under 35 U.S.C. § 134 from a final rejection of claims 1, 3-19 and 21-24 (Br. 2). Claim 27 is not properly before us.[2] Claims 25 and 26, the only other pending claims, have been withdrawn from consideration. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

The subject matter on appeal is directed to an oral dosage form, such as a tablet, comprising an active ingredient(s), such as a drug or vitamin, and a formulated mixture of polyvinyl acetate ("PVAc") and polyvinylpyrrolidone ("PVP"), wherein the formulated mixture facilitates delayed release of the active ingredient(s). Claim 1 is illustrative and reads (Br. 9):

> 1. An oral dosage form with delayed release of active ingredient and high mechanical stability, comprising
>
> a) one or more active ingredients
>
> b) from 20 to 80%, based on the total weight of the dosage form, of a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone
>
> c) water soluble polymers or lipophilic additives
>
> d) and other conventional excipients,
>
> wherein the ratio of polyvinyl acetate to polyvinylpyrrolidone is from 6:4 to 9:1 and said formulated mixture of polyvinyl acetate and

[2] As set forth in 35 U.S.C. § 134 in relevant part, "An applicant for a patent, any of whose claims has been twice rejected, may appeal from the decision of the primary examiner to the Board . . . ." In this case, pending claim 27 has never been rejected by the Examiner. Thus, there is no decision of the Examiner in regard to claim 27 to appeal to the Board.

polyvinylpyrrolidone facilitates said delayed release.

The Examiner relies on the following references[3] of record:

Ortega	4,837,032	Jun. 6, 1989
Kolter	6,066,334	May 23, 2000
Kolter DE	DE 197 09 663 A1	Sep. 17, 1998

Remington: THE SCIENCE AND PRACTICE OF PHARMACY, 19th edition, Mack Publishing Company, Easton, Pennsylvania, pp. 1617-1618 (1995).

The Examiner rejected claims 1, 3-19, and 21-24 under 35 U.S.C. § 103(a) as unpatentable over Kolter DE 197 09 663 A1, "for which US 6,066,334 is relied on as a translation," in view of Ortega (FR[4] 2; Ans.[5] 3).

The Kolter patent issued based on application 09/037,796, filed March 10, 1998. Since Kolter qualifies as prior art under 35 U.S.C. § 102(e), we base our decision on Kolter, rather than Kolter DE.

On appeal, the initial procedural burden is on the Appellant to demonstrate reversible error in the Examiner's rejection. Arguments that could have been raised in the principal brief on appeal but were not raised therein are deemed to have been waived, absent a showing of good cause. In addition, any evidence that the Appellants intend to rely on in support of arguments made in the principal brief on appeal must be included in the Evidence Appendix. 37 C.F.R. § 41.37(c)(1)(ix). Since Appellants did not present separate patentability arguments for any of claims 1, 3-19, and 21-

[3] The reader is advised that no references to *et al.* are made in this decision.
[4] Office Action mailed 26 February 2007 ("FR").
[5] Examiner's Answer mailed 29 November 2007 ("Ans.").

24, we decide this appeal on the basis of claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

II. Findings of Fact ("FF")

The following findings of fact and those set forth in the discussion are supported by a preponderance of the evidence.

A. Appellants' specification

[1] According to the 546 specification, a "formulated mixture of polyvinyl acetate and polyvinylpyrrolidone is . . . an intimate mixture of a lipophilic with a hydrophilic polymer" and is known in the art (Spec. 3:17-21).

[2] The Examples in the 546 specification describe a formulated mixture of PVAc and PVP in a 8:2 ratio available as "Kollidon® SR" (Spec. 10:29-30; 11:46-12:1; 13:11-12; 14:30-32; 15:38-40; 16:45-46).

[3] "Medicinal substance matrices based on a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone gradually form, during passage through the stomach and intestines, fine pores through which the medicinal substance slowly diffuses out" (Spec. 3:23-26).

[4] "The inert excipient matrix is free of active ingredient is then excreted . . ." (Spec. 3:26-28).

[5] The 546 specification does not define "delayed release."

[6] Example 6 of the 546 specification is said to show that 25.3% of the active ingredient in a tablet consisting of 320 g of propranolol HCl, 320 g of Kollidon® SR, and 6.4 g of magnesium stearate was released when tested at 1 hour using a USP XXIV method release test (Spec. 16:40-17:15; Table 12, 18:9).

B. Kolter

[7] Kolter discloses a binder consisting of (a) 10-95 wt.% PVAc, (b) 5-90 wt.% PVP-containing polymer, (c) 0-20 wt.% water-soluble or water swellable substance and (d) 0-20 wt.% water-insoluble dusting agent with or without (e) other additives for producing solid pharmaceutical products, wherein the binder "is from 0.5 to 20 % by weight" (Kolter 2:23-36).

[8] According to Kolter, PVAc and PVP are not miscible in each other, so "for good binding activity the polyvinyl acetate must be very finely distributed in the product" (Kolter 2:57-62).

[9] Kolter discloses weight ratios of PVAc:PVP "in the range from 95:5 to 10:90" (Kolter 4:11-13).

[10] The product may contain other water-soluble polymers, preferably polyvinyl alcohol and hydroxypropylmethylcellulose, and other ancillary substances, such as bulking agents, flow regulators, disintegrants and lubricants (Kolter 4:14-17, 31-32, and 59-63).

[11] Kolter discloses using PVAc:PVP in an 80:20 ratio by weight as a dry binder in an ascorbic acid tablet (Kolter 5:65-67).

[12] According to Kolter, the pharmaceutically active ingredient is released from the product "within a time of from 0.1 to 1 hour, as measured in simulated gastric acid . . . where binder content is from 0.5 to 20% of the total weight. . ." (Kolter claim 1, 7:59 - 8:15).

C. Ortega

[13] Ortega discloses a delayed release theophylline tablet comprising (a) 43 to 50 wt.% theophylline, (b) 10 to 20 wt.% water insoluble polymer, preferably PVAc, (c) 10 to 15 wt.% water soluble polymer,

preferably PVP, and (d) 5 to 15 wt.% acid insoluble polymer having carboxylic groups, preferably cellulose acetate phthalate (Ortega 2:68-3:10; 3:28-30, 35-42, 46-50, 53-55).

[14] According to Ortega the PVAc "serves as a retardant against drug dissolution", the cellulose acetate phthalate "retards drug dissolution in the stomach while allowing dissolution in intestinal fluid", and the PVP "swells and dissolves thereby permitting controlled drug dissolution as the gastro-intestinal fluids penetrate and erode the tablet" (Ortega 3:11-17).

D. The Examiner's findings of fact

[15] The Examiner found that Kolter discloses the claimed invention but for "a teaching of PVAc/PVP that is 20-80% of the total weight. Kolter . . . only slightly overlap[s] with this range, teaching up to and including 20% PVAc/PVP." [Ans. 4.]

[16] The Examiner found that Ortega discloses drug formulations using PVP/PVAc mixtures as binders "in different amounts than in Kolter...and the result[ing] formulations with more binder have longer release profiles" (Ans. 4-5).

III. Discussion

A. The Examiner's *prima facie* conclusion of obviousness

The Examiner concluded it would have been *prima facie* obvious to vary the amount of binder in Kolter in order to optimize the release profile because the combined teachings of Kolter and Ortega show that the amount of binder is a result-effective variable that could be adjusted depending on the intended use of the final product (Ans. 5).

B. Appellants' position

According to Appellants, Kolter makes it clear that its binder content is to be less than 20 wt.% to achieve rapid release of the active ingredients from the product (Br. 3-4). Further according to Appellants, Ortega's sustained release tablets comprise not only a water insoluble polymer [e.g., PVAc] and a water soluble polymer [e.g., PVP], but also an acid insoluble polymer having carboxylic acid groups [e.g., cellulose acetate phthalate] (Br. 4-5). Appellants assert not only that the preamble of claim 1, "An oral dosage form with delayed release of active ingredient ...", is a claim limitation, but also that they have clearly relied on the preamble during prosecution to distinguish over the cited prior art (Br. 5-6). Thus, Appellants argue the Examiner erred in failing to accord the preamble of claim 1 patentable weight (Br. 5; Reply 4-5). Appellants further argue that combining Ortega with Kolter would change the principle of operation of Kolter, rendering Kolter unsatisfactory for its purpose of rapid drug release (Br. 7; Reply 4-6), and yield unpredictable results (Reply 2-3). Appellants still further argue that Ortega has nothing to do with optimizing the rapid release times of Kolter (Br. 7). Appellants finally argue that neither Kolter nor Ortega disclose a formulated mixture of PVP and PVAc as required by the appealed claims (Br. 7-8).

C. Legal principles

A claimed invention is not patentable if it would have been obvious to a person of ordinary skill in the art. 35 U.S.C. § 103(a); *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). Facts relevant to a determination of obviousness include: (1) the scope and content of the prior art, (2) any differences

between the claimed invention and the prior art, (3) the level of ordinary skill in the art and (4) relevant objective evidence of nonobviousness. *KSR*, 127 S.Ct. at 1734; *Graham*, 383 U.S. at 17-18. All claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 984 (CCPA 1974). Finally, limitations from the specification are not read into the claims. *In re Prater*, 415 F.2d 1393, 1404 (CCPA 1969) ("reading a claim in the light of the specification" is a quite different thing from "reading limitations of the specification into a claim").

D. Analysis

Claim 1 requires a formulated mixture of PVAc and PVP wherein the mixture "facilitates said delayed release". Delayed release of the claimed oral dosage form is a limitation positively recited in the body of the claim. Therefore, whether or not the preamble of claim 1 is entitled to patentable weight is a moot point. Regardless, as noted by the Examiner (Ans. 7), "[e]ven if the preamble is afforded patentable weight, the limitation of delayed release is met by the prior art."

As the Examiner points out (Ans. 7), Appellants' specification does not define the term "delayed release" (FF 5). Appellants contend the specification shows that at most 25.3% of active ingredient is released after 1 hour and typically 64.4% is released after 16 hours (Reply 5).[6] It is

[6] "Delayed release" versus "immediate release" was argued by Appellants in their principal brief (see e.g., Br. 5-7). For the first time in the Reply Brief the Appellants rely on two references, Gundert-Remy and USP 23 1880, filed in response to the Office action mailed June 30, 2005, to establish that the terms "delayed release" and "immediate release" are terms of art (Reply 5). The Appellants did not include copies of either reference in the Evidence Appendix of the Appeal Brief or show good cause why these two references were not relied on as evidence in their principal brief. Therefore, the two

improper to read limitations of the specifications into the claim. Therefore, we decline to interpret "delayed release" as requiring no more than 25.3% of active ingredient release after 1 hour or any other % release per unit time exemplified in the 546 specification into the appealed claims.

Furthermore, delayed versus rapid versus immediate are relative terms. Appellants have not explained why release of an active agent from the product having a binder content of 20 wt.% within 1 hour as disclosed by Kolter (FF 12) is not a "delayed release" within the scope of the claimed invention. Kolter discloses a solid pharmaceutical product comprising 20 wt.% of a PVAc/PVP binder (FF 7) in a suggested 80:20 ratio (FF 11). Claim 1 recites an oral form product comprising 20 to 80 wt.% of a PVAc/PVP binder in a 6:4 to 9:1 ratio. Indeed, insofar as Kolter discloses the same binder of PVAc and PVP as the claimed formulated mixture of PVAc and PVP, products of identical chemical composition cannot have mutually exclusive properties. *See In re Papesch*, 315 F.2d 381, 391 (CCPA 1963) (a chemical compound and its properties are inseparable). Thus, Appellants have not established that Kolter does not teach or suggest a delayed drug release embodiment within the scope of claim 1.

Moreover, it is well settled that a reference must be considered in its entirety, and it is well-established that the disclosure of a reference is not limited to preferred embodiments or specific working examples contained therein. *See In re Fracalossi*, 681 F.2d 792, 794 n.1 (CCPA 1982); *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976). Kolter discloses that the binder "is from 0.5 to 20 % by weight" (Kolter 2:23-36). Thus, it is improper to

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references and the Appellants' arguments based on the two references are not entitled to consideration on appeal and will not be considered in this appeal.

limit the disclosure of Kolter to products having binder contents of less than 20 wt.%.

Next, the Examiner relies on Remington to rebut Appellants' argument that the effect of combining Ortega with Kolter is unpredictable. As explained by the Examiner (Ans. 5-6), Remington teaches that binders are known to affect the disintegration rate of tablets (Remington 1617). The fact that some experimentation may be necessary to optimize a particular binder content to optimize a desired active agent release profile does not *per se* render the experimentation unpredictable. The Examiner pointed to the Examples in Ortega and Kolter as teaching that increasing the amount of PVAc/PVP binder will increase the release profile of the active agent (Ans. 6). Notably, Ortega also teaches PVAc "serves as a retardant against drug dissolution" and PVP permits "controlled drug dissolution as the gastro-intestinal fluids penetrate and erode the tablet" (FF 14).

Appellants apparently point to a teaching in Kolter at column 1, lines 21-28, discussing the importance of the amount and nature of the binder and the processing method on the properties of manufactured products, in rebuttal of Remington. Appellants have not explained how this general discussion relates to teachings in Kolter and Ortega regarding specific amounts of a particular PVAc/PVP binder.

Finally, according to the 546 specification, a formulated mixture of PVAc and PVP is "an intimate mixture of a lipophilic with a hydrophilic polymer" (FF 1). According to Kolter, PVAc and PVP are not miscible in each other and so the PVAc "must be very finely distributed in the product" (FF 8). The Examiner found Ortega claim 12 and Kolter Example 1 teach forming mixtures of PVAc and PVP within the scope of a "formulated

mixture" as claimed (Ans. 7-8). Appellants did not contest the Examiner's finding in their reply brief.

Appellants have not submitted relevant evidence of nonobviousness.

Based on the foregoing, we AFFIRM the rejection of claims 1, 3-19, and 21-24 under § 103 as unpatentable over Kolter in view of Ortega.

IV. Order

Upon consideration of the record, and for the reasons given, it is

ORDERED that the decision of the Examiner rejecting claims 1, 3-19, and 21-24 under 35 U.S.C. § 103(a) as unpatentable over Kolter in view of Ortega is AFFIRMED; and,

FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a) (2006).

AFFIRMED

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